

AMENDMENTS TO THE CLAIMS

1-48 (Canceled).

49 (Currently Amended). A method for treating ~~on-demand~~ at least one symptom of gastro-esophageal reflux disease (GERD) in a human comprising

(i) identifying a proton pump inhibitor ~~or a salt thereof~~ (PPI) selected from a group consisting essentially of ~~acid-activated agents that inhibit the gastric H⁺,K⁺-ATPase enzyme~~ lansoprazole, omeprazole, pantoprazole, rabeprazole, pariprazole, leminoprazole, and their pharmaceutically acceptable salts, isomers including enantiomers, and pharmaceutically acceptable salts of said isomers,

(ii) identifying an H₂ receptor antagonist ~~or a salt thereof~~ (H₂RA) selected from a group consisting essentially of ~~agents that inhibit action of histamine on H₂ receptors on parietal cell surfaces~~ cimetidine, ranitidine, nizatidine and famotidine, and their pharmaceutically acceptable salts, isomers, and pharmaceutically acceptable salts of said isomers,

(iii) adopting an oral dose regime comprising:

(a) selecting an oral dosage form for the H₂RA for release of H₂RA in a gastro-intestinal tract;

(b) selecting an oral dosage form for the PPI for release of PPI in the gastro-intestinal tract and that, when orally administered to the gastro-intestinal tract ~~concomitantly~~ concurrently with the H₂RA, delays and/or extends the release of the PPI relative to the release of the H₂RA;

~~(c) orally administering concomitantly the selected oral dosage forms of the H₂RA and the PPI to affect a rise in gastric pH to above about 3 within about 2 hours of administration,~~

(iv) ~~on-demand, based upon an occurrence of at least one symptom of GERD,~~ orally administering the selected oral dosage forms of the PPI and the H₂RA ~~concomitantly~~ concurrently according to the dose regime to affect a rise in gastric pH to above about 3 within about 2 hours of administration, thereby treating at least one symptom of GERD promptly, and

(v) repeating (iv) ~~on-demand, based upon a subsequent occurrence of at least one symptom of GERD,~~ if necessary over a prolonged period until 6 hours from the administration of the last dose.

wherein the at least one symptom of GERD is selected from a group consisting of heartburn, sour stomach, and upper abdominal pain.

50-86 (Canceled).

87 (Currently Amended). A method as claimed in claim 49, wherein (iii)(a) and (iii)(b) comprise selecting separate oral dosage forms for the H2RA and the PPI, and wherein ~~iii(c) and~~ (iv) comprises orally administering the separately oral dosage forms ~~concomitantly on demand~~ concurrently.

88 (Currently Amended). A method as claimed in claim 87, wherein the separate oral dosage form for the PPI ~~comprises~~ is a tablet or capsule within which the PPI is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

89 (Currently Amended). A method as claimed in claim 49, wherein (iii)(a) and (iii)(b) comprise combining the oral dosage forms for the H2RA and the PPI into a single oral dosage form, and wherein ~~(iii)(c) and~~ (iv) comprises orally administering the single oral dosage form ~~on demand~~.

90 (Currently Amended). A method as claimed in claim ~~88~~ 89, wherein the single oral dosage form ~~comprises~~ is a tablet or capsule within which the PPI is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

91 (Previously Submitted). A method as claimed in claim 90, wherein the tablet or capsule further comprises a pharmaceutically acceptable excipient.

92 (Previously Submitted). A method as claimed in claim 91, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

93 (Cancelled).

94 (Currently Amended). A method as claimed in claim 89, wherein the single oral dosage form includes a core comprising the PPI and a membrane including an excipient applied onto the core ~~that delays and/or extends the release of the PPI relative to the release of the H2RA.~~

95 (Previously Submitted). A method as claimed in claim 94, wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

96 (Currently Amended). A method as claimed in claim 94, wherein the single oral dosage form ~~comprises~~ is presented as a tablet or capsule within which the core and the membrane

are presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

97 (Currently Amended). A method as claimed in claim 94, wherein the single oral dosage form ~~comprises is presented in~~ two halves, ~~one of which comprises one or more of the cores and membranes, and the other half comprises the H2RA.~~

98 (Previously Submitted). A method as claimed in claim 97, wherein the H2RA half includes a pharmaceutically acceptable excipient.

99 (Previously Submitted). A method as claimed in claim 98, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

100 (Previously Submitted)). A method as claimed in claim 97 or 98, wherein the H2RA forms an outer layer applied onto the membrane of the core.

101 (Previously Submitted). A method as claimed in claim 94, wherein the H2RA forms an outer layer applied onto the membrane of the core, and wherein the single dosage form includes an alkaline-reacting substance admixed with the PPI.

102 (Previously Submitted)). A method as claimed in claim 94, wherein the single dosage form includes an enteric coating layer applied onto the membrane.

103 (Previously Submitted). A method as claimed in claim 102, wherein the single dosage form includes a layer separating the enteric coating from the membrane.

104 (Previously Submitted). A method as claimed in claim 102 or 103, wherein the H2RA forms an outer layer applied onto the membrane of the core.

105 (Currently Amended). A method as claimed in claim 89, wherein the PPI of the single oral dosage form ~~includes is presented as~~ a matrix comprising the PPI and an excipient ~~incorporated with the PPI to delay and/or extend the release of the PPI relative to the release of the H2RA.~~

106 (Previously Submitted). A method as claimed in claim 105, wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

107 (Currently Amended). A method as claimed in claim 105, wherein the single oral dosage form ~~comprises is~~ a tablet or capsule within which the matrix is presented as a plurality of small dosage units comprising pellets, granules or beads distributed within the tablet or capsule.

108 (Previously Submitted). A method as claimed in claim 105 or 107, wherein the H2RA forms an outer layer applied onto the matrix.

109 (Previously Submitted). A method as claimed in claim 105, wherein the H2RA forms an outer layer applied onto the matrix, and wherein the single oral dosage form includes an alkaline-reacting substance admixed with the PPI.

110 (Currently Amended). A method as claimed in claim 105, wherein the single oral dosage form ~~comprises~~ is presented in two halves, ~~one of which comprises the matrix, and the other half comprises the H2RA.~~

111 (Previously Submitted). A method as claimed in claim 110, wherein the H2RA half includes a pharmaceutically acceptable excipient.

112 (Previously Submitted). A method as claimed in claim 111, wherein the pharmaceutically acceptable excipient comprises a disintegrant.

113 (Previously Submitted). A method as claimed in claim 105, wherein the single dosage form includes an enteric coating layer applied onto the matrix.

114 (Previously Submitted). A method as claimed in claim 113, wherein the single dosage form includes a layer separating the enteric coating from the matrix.

115 (Previously Submitted). A method as claimed in claim 113 or 114, wherein the H2RA forms an outer layer applied onto the matrix.

116 (Currently Amended). A method as claimed in claim 49, wherein at least one of the selected oral dosage forms further comprises an antacid agent ~~and/or~~ or an alginate.

117 (Currently Amended). A method as claimed in claim 116, wherein the antacid agent comprises at least one of aluminum hydroxide, calcium carbonate, magnesium carbonate, basic magnesium carbonate, magnesium hydroxide, magnesium oxide ~~and/or~~ or sodium hydrogen carbonate.